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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,283	11/13/2001	Carl-Axel Bauer	06275-150003	5064

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EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1628

NOTIFICATION DATE	DELIVERY MODE
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03/05/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/010,283	Applicant(s) BAUER ET AL.	
	Examiner JENNIFER M. KIM	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/12/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 11-17 and 21-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 11-17 and 21-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>see attached</u> . | 6) <input type="checkbox"/> Other: _____ |

12/22/2009;11/16/2009;11/12/2009

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicants' submission filed on November 12, 2009 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1628

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 11-17 and 21-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smeenk et al. (Full English translation of Smeenk et al.(Nederland Tijdschrift Geneeskunde Vol. 13, January Issue 140(2), **1996** pages 94-98) in view of Carling (WO 93/11773) of record.

Smeenk et al teach that a 66-year-old man, was being treated for a moderately severe COPD with formoterol 12ug 2 times a day and budesonide 800ug 2 times a day via an inhaler (Turbuhaler) (see page 4 of English translation). These amounts are within Applicants ratio set forth in the claims.

Smeenk et al. do not teach the simultaneous administration of formoterol and budesonide, fumarate dihydrate salt, and specific dosages of the active ingredients.

Carling et al. on the abstract, page 4, lines 23-29, page 7 through 9 (examples), and page 10 (claims), teach that the formoterol and budesonide are available in a single medicament for simultaneous administration by inhalation in the treatment of respiratory disorder with effective amounts within Applicants' range set forth in the claims. Carling et al. teach that the combination comprising formoterol and budesonide has not only a greater efficiency and duration of bronchodilator action but the combination also has a rapid onset of action and this new feature is of utmost important in order to establish a higher compliance of patients and it improves a rescue medicine thereby avoiding the necessity for the patient carrying two different inhalers (page 4, lines 4-10). Carling et al. teach that the combination of formoterol and budesonide in a single formulation

Art Unit: 1628

simplifies life for patients considerably and makes life more comfortable and secure in treating respiratory disorder (page 4, lines 10-12, lines 23-29).

It would have been obvious to one of ordinary skill in the art to employ the Carling's medicament in the treatment of COPD in the COPD patient disclosed by Smeenk et al. One would have been motivated to make such a modification in order to achieve and expected benefit of the Carling et al's medicament comprising both formoterol and budesonide not only providing greater efficiency and duration of bronchodilator action but also provide higher compliance and improves a rescue medicine thereby avoiding the necessity for the patient carrying two different inhalers. There is a reasonable expectation of successfully treating COPD in the patient disclosed by Smeenk et al. because they are drawn to same technical fields (constituted with same active ingredient, the same effective amount and the same route of administration) and pertinent to the problem which applicant concerns about for the treatment of COPD. MPEP 2141.01(a). The amounts of active agents to be used, the pharmaceutical salts, e.g., fumarate dihydrate salt, etc; mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration. Furthermore, no unobviousness is seen in the ratio claimed because once the usefulness of a compound is known to treat a condition, it is within the skill of the artisan to determine the optimum ratio.

None of the claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1628

Application/Control Number: 10/010,283

Page 6

Art Unit: 1628

Jmk

February 1, 2010